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9629 7590 11/20/2007 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			EXAMINER KOSAR, AARON J	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/649,742	Applicant(s) KAIMAL ET AL.	
	Examiner Aaron J. Kosar	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 9 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 9 and 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. 09/207,056.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Arguments

Applicant's amendment and argument filed August 20, 2007 in response to the non-final rejection, are acknowledged and have been fully considered.

Applicant has amended the claims by canceling claims 6, 8, and 10 and introducing new claims 12-15. Applicant's arguments filed August 20, 2007 have been fully considered but they are not persuasive for the reasons of record and for the arguments below. Any rejection and/or objection not specifically addressed is herein withdrawn.

Claims 1-5, 7, 9, and 11-15 are pending and have been examined on the merits.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e), 120, 121, or 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original non-provisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/207,056 (" '056", Now US 6,617,141 B1), fails to provide adequate support or enablement in the manner provided by

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the first paragraph of 35 U.S.C. 112 for one or more claims of this application, because the instantly pending Application is drawn to new matter which was not recited in the prior-filed '056 application, especially with respect to the terms "about" and "around" and the value "5.35 kcal/g".

Additionally, the instant claims and the disclosure (page 13, ¶1 through page 23, table 5 inclusive) possess subject matter not recited in the certified copy of the English-language Foreign Priority Document (IN 3504/DEL/97).

Presently, claims 1-4, 7, and 9-11 contain or depend from claims having new matter and are acknowledged as having priority to the instant filing date, August, 28, 2003. The subject matter of claim 5 is supported by the original '056 application and is acknowledged as having priority to December 8, 1998.

Specification

The amendment filed 8/28/2003 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure of the Divisional. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. Although the application is a divisional of 09/207,056, the added material which is not supported by the original disclosure in the '056 Application which was added to the instant specification is as follows: the terms "about" and "around", the value "5.35 kcal/g", and the ranges recited in claims 7 and 9.

Applicant is required to cancel the new matter in the reply to this Office Action *or* forfeit the priority to the parent '056 Application by properly declaring the instant application as a continuation in part (CIP).

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Claim Objections

Claims 2 and 11 are objected to because of the following informalities:

In claim 2, Applicant recites the Abbreviation SFI. Since abbreviations may have multiple meanings and because the claim contains the phrase *solid fat index*, to avoid potential confusion, Applicant is required to recite the phrase “solid fat index (SFI): ” to correlate the abbreviation with the first-recited expanded version of the abbreviation in the claims.

In claim 11, Applicant’s amendment to cancel the word “enzyme” from the recitation of “a thermostable lipase [enzyme]” is inconsistent with the subsequent recitation of “the thermostable lipase enzyme”. Since the terms lipase and lipase enzyme are similar in meaning, cancellation of the word *enzyme* from the phrase “the thermostable lipase enzyme” in claim 11 would be sufficient to overcome this ground of rejection and would avoid potential confusion as to the meaning and antecedence of the terms in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-5, 7, 9, and 12-15 rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is **not enabling**. A representative/working example of making or obtaining the claimed composition is minimally required for the claims to be enabled; however, none of the compositions, to the extent claimed, is recited, supported, or unambiguously exemplified by the disclosure such that the disclosure does not reasonably teach or make obvious to one of skill how to make and use the claimed composition. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

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The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a composition comprising combinations of palmitic, stearic, oleic, linoleic, arachidic, behenic, and lignoceric acid in flexible relative proportions. Claim 5 is drawn to a 6-component fatty acid composition. Claim 11 is drawn to a myriad of possible structured fat compositions having 1,3-rearrangement character and 1,3-beheninc acid enrichment.

The disclosure of the instant application teaches a method of producing a behenic, oleic, and linoleic acid-containing TAG composition and provides tables which list other embodiments which further list additional components and specific proportions of the elements including the inherent/calculated properties therein.

Thus, the claims taken together with the specification imply a much broader breadth than what is supported by the instant disclosure.

(3) The state of the prior art; (4) the predictability or unpredictability of the art; and (5) the relative skill of those in the art:

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The relative skill of those in the art is high. The components of rapeseed (mustard) safflower and sunflower oils reagents have also been reported in GUNSTONE (Gunstone, F, et al. The Lipid Handbook. 1994. Chapters 3.3.27, 3.3.29, and 3.3.35. (see itemized tables therein)) ; however, since the *a priori* prediction of the product distribution of a 1,3-enzymatic randomization/interesterification remains largely unsolved, means for making the composition are highly unpredictable and thus beyond the purview of one of skill, especially to the extent of predicting/making compositions with the desired/claimed properties and claimed product distributions and in all instances. For example it is beyond the purview of the skilled artisan to react a sunflower oil - which intrinsically possesses <0.3wt% C24:0 (lignoceric acid) (see tables 3.127, 3.128) – wherein the sunflower oil is reacted with behenate/behenic acid and a 1,3-lipase to produce a behenic-enriched TAG compositions concomitant with an elevated (1.6 wt%) lignoceric acid content.

(6) *The amount of direction or guidance presented and (7) the presence or absence of working examples:*

The specification has provided a method of making an oleic/linoleic/behenic acid-containing composition (example 5). The disclosure also recites the products containing:

- 1) 7+ components: palmitic, stearic, oleic, linoleic, arachidic, behenic, and lignoceric acid (e.g. ¶[0040], claim 1);
- 2) 5+ components: behenic, palmitic, linoleic, oleic, and stearic acids (e.g. ¶ [0043], claim 4);
- 3) 6 + components: behenic, palmitic, linoleic, stearic, arachidic, and lignoceric acids (e.g. claim 5); or
- 4) 3+ components: behenic, oleic, linoleic, and “other” fatty acids (examples 1-12);

however, the specification does not provide or correlate the recited compositions (claims; (1)-(3) above) with a working example or method ((4) above) which would yield the claimed compositions *and* in the desired component proportions of all of the claimed elements.

Additionally, the working example and method most closely related to the claimed

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composition(s) appears to be exclusive to the proportions of a sunflower oil enriched by reacting with an alkyl behenate, especially with an ethyl behenate.

Furthermore, claim 4 appears to be incompatible with the composition recited in claim 1, because it is unclear how a composition comprising 3.3% by weight Arachidic (C20:0) acid plus Lignoceric (C24:0) acid, wherein 100% of the wt% is accounted for (sum of claimed components), could at the same time be further limited by a composition having a total of 99.8% behenic (B, C22:0), palmitic (P, C16:0), linoleic (L, C18:2), oleic (O, C18:1) plus stearic (S, C18:0) and thus only 0.2% of total molecular species of C20:0, C24:0, or other fatty acids (see also 35 U.S.C. 112, 2nd ¶, below).

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed above by Gunstone and the high unpredictability and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to make and use the invention as claimed.

It is the Examiner's position that one skilled in the art could not practice the invention commensurate in the scope of the claims without undue experimentation.

Claims 1-5, 7, 9, and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention ("**new matter**").

MPEP § 2163 states that, "[n]ew or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus

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range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389,1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).” Further, the MPEP states, “[w]hile there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.”

Please see *Gentry Gallery v. Berkline* 45 U.S.P.Q.2d 1498 for a discussion related to broadening the claimed invention without support in the as-filed specification. Also, please see *PurduePharma v. Faulding* 56 U.S.P.Q.2d 1481 for a discussion related to a failure to describe a claimed generic concept in the narrative portion of the specification, but rather basing support on limitations in examples.

In the instant case, Applicant has amended claim 4 from the scope of “wt%” to recite “% total molecular species”; however, the amendment, while addressing the ambiguity of the relative versus absolute reference of the unit of measure as argued in the previous Office action, is not supported by the original disclosure. The unit of measure wt% is based on mass:mass (w/w) or mass:volume (w/v) ratios whereas the unit of measure % of *total molecular species* is based on a ratio of moles:moles (n:n) which is not equivalent to the expression “wt%”. Thus the unit of measure and the corresponding values as recited are rejected for introducing new matter into the claims.

In the instant case, also Applicant has amended claims 1, 3, 4, 7, 9, and 11-15 by amending the scope of the claims from exacting measurements of wt%, temperatures, and % molecular species to introduce the broader-scoped terms “about” or “around” and adding to the claims the broadened ranges of “about 24.7% to 34.7%”, “about 33.7% to 51.5%”, and “around

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5.35 Kcal/g". However, it is noted that the specification does not support the terms "about" and "around" or the expanded ranges and values above (*i.e.* 24.7-34.7%; 33.7-51.5%; or 5.35 Kcal/g) in relation to the claimed composition. There is an insufficient number of species and working examples correlated to the claimed composition(s), such that the disclosure cannot provide support for all ranges of wt%, temperature, or % of molecular species as claimed. Further, the specification does not define the terms "about" or "around" and there is no express, implicit, or inherent disclosure to support the broader-claimed ranges as instantly claimed. Thus, the term "about" and "around" the value "5.35 Kcal/g" and the claimed temperature ranges (*supra*) are rejected for introducing new matter into the claims.

Applicant has also amended claim 11 to recite the limitation of LYPOZYME in terms of generic identification. Because LIPOZYME is trademarked and appears to be a single enzyme entity, and because Applicant's amendment to the claim is required to be of equal scope, the recitation of "from sources including *M.miehei*" expands the scope of the claims to the entire genus of 1,3-lipases. The claim is rejected because this expansion of scope introduces new matter into the claims and is not supported by the original disclosure. Please note, however, that this ground of rejection may be overcome by reciting "...wherein the thermostable lipase is the 1,3-specific lipase from *M. miehei*, LIPOZYME™."

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-5, 7, 9, and 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The recitation of the phrases “A fatty acid composition of structured fat comprising:” and “ a structured fat composition which comprises palmitic acid, ..” are indefinite. The phrases are indefinite, because it is unclear if the claims are drawn to a fatty acid-containing structured fat composition, wherein the fatty acids are associated with triacylglycerides (TAGs or structured fats). In the alternative the claims may be reasonably drawn to fatty acids compositions *per se* obtainable from structured fats (TAGs) but not requiring the TAG structure (e.g. free fatty acids). Each interpretation is a reasonable interpretation of the claims although each defines different metes and bounds of the claimed invention. Thus one would not be apprised as to the subject matter Applicant intends to claim, rendering the claims indefinite.

Please note, claim 4 does not remediate this ambiguity in claim 1, because the composition as recited *comprise* the components and it may be broadly and reasonably interpreted that the claimed composition may include both a free fatty acid fraction (e.g. the components of claim 1) and the additional elements of a TAG fraction (e.g. the components of claim 4) in the same composition measured separately.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended claim 1 to recite a wt% of fatty acid in a structured fat (triacylglyceride (TAG)). Please note, the relative term “%” requires a reference unit of measure. Since weight percent is recognized in the art as proportion of partial component “A” versus total composition/component “B” (by mass = grams per 100 grams (w/w)) or by the equivalent expression by volume =grams per 100 mL (w/v)) wherein the identity of “A” is a fatty acid and

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“B” is a TAG composition, the rejection of the claim on this ground of rejection is rendered *moot*.

However, Applicant's has also amended claim 4 by canceling the term “Expected”. It is unclear whether the TAGs listed are supported by the specification and claims, because it is unclear which term, “Effective Carbon Number” *or* “TAG”, is the controlling parameter in defining the HPLC-characterized composition. Because of the listing of a series of TAGs by a semicolon “;” and because of the method of analysis (claimed: HPLC; disclosed: HPLC, GC, Si column chromatography) it is unclear whether the TAG pairs identified as C46 (SLL;POL) and C48 (SOL;OOO) are *known* to contain all four triacylglycerides (SLL *and* POL and SOL *and* OOO) or if the triacylglycerides recited are merely exemplary of the desired and most likely C46 and C48 fraction candidates (The latter instance which thus may include the combinations of SLL *or* POL and SOL *or* OOO). Since each interpretation is a reasonable interpretation of the claims and each defines different metes and bounds, it is unclear what subject matter is embraced by the claims thus rendering the claims indefinite.

Please note, it is unclear as to whether the composition of claim 4 (0.2% non-B/P/L/O/S) corresponds to the composition of claim 1 (3.3% Arachidic/Lignoceric = “non-B/P/L/O/S”) from which it depends. Thus Applicant's response to claim 4 should include cancellation of the claim(s) *or* amendments and evidence/arguments as to how the values in the two claims are compatible in describing a further limitation of the same/single composition of claim 1 (e.g. Is this an artifact of column chromatography/HPLC/GC, etc? Is such a method of measurement of wt% in claim 1 supported in the specification?).

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Claims 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "delivery" of about 5.35 Kcal/g; however, it is unclear from the specification and the claims what constitutes delivery, what is the object of the delivery, what conditions (reaction(s), etc.) are necessary to elicit a delivery, and/or what compositions are embraced by the further-undefined range of "about 5.35" Kcal/g. Thus one of skill would not be apprised of the metes and bounds of the claims or the compositions which Applicant intends to claim, rendering the claims indefinite. Please note, the caloric values as presented in the disclosure appear to be intrinsic properties of compositions relative to the passage of said compounds through the GI tract of a specific organism and subsequent relative weight gain therein. Therefore to overcome this ground of rejection, to the extent a value which is supported in the specification may be correlated to a specific composition, Applicant is also required to identify the organism in which the energetic/caloric value is determined/referenced (e.g. when fed to a rat, human, etc.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over CAIN (B: PTO-892, 3/20/2007: US 5,654,018).

Claim 11 is drawn to a fat composition product by the process of esterification of edible oil(s) with 1,3-dibehenin.

While CAIN (Claim 1) claims a process for producing a "SUS" triacylglyceride composition which involves a different process with different manipulations and different recited steps than the process of the presently claimed invention - such as in the case where Cain's process results in the SUS product 2-oleo 1,3-dibehenin (BOB) - the product of Cain's process would still be identical in structure to the product produced by the process of the presently claimed process of claim 11. See MPEP 2113.

Applicant's arguments that the composition of Cain differs from the composition of the instant claims have been fully considered. Applicant's arguments are persuasive to the extent that the composition is silent regarding the recitation of the identical conditions of the *process* within the instant claims. The composition, however, is not limited by the process recited, but only by the structural contributions provided therein.

Therefore, since Cain teaches a composition which contains the structured fat (triacylglyceride) BOB which, though produced by a different method, Cain still meets the minimum requirement of the instantly claimed *composition*. It would have been obvious to use the method of Cain because Cain teaches a structured fat having 1,3-behenic fatty acid group and a 2-oleic fatty acid group comprising the triacylglyceride. One would have been motivated by Cain to make a triacylglyceride structured fat, because the method of Cain teaches making

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Saturated-Unsaturated-Saturated (SUS)-containing compositions, including BOB. One would have had a reasonable expectation of success in making a structured fat composition because Cain teaches making a structured fat composition, including BOB-containing compositions. Thus the instantly claimed composition would have been obvious in view of the teaching of Cain, especially in the absence of evidence to the contrary.

Claims 1-5,7,9,and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over MAZUR (US 5,116,745).

The claims recite a composition comprising a behenic enriched composition of fatty acids as recited in claim 1 and triglycerides as recited in claim 4. The claims also recite a composition comprising palmitic, stearic, linoleic, arcahidic, lignoceric, and behenic acids (C16:0, C18:0, C18:2, C20:0, C22:0, and C24:0 respectively).

Mazur teaches using 1,3 specific lipases to make a variety of triglycerides with fatty acid esters of R, R', and R'', wherein R and R'' are in the 1 and 3 positions and R' in the 2 position. Mazur teaches the fatty acids of the resultant di- and triglycerides comprise 2-24 chain length fatty acid carbons atoms, preferable 8-24 carbon atoms, including C18,C20, C22, or C24 or mixtures thereof based on a conserved 2-acylglyceride structure. Mazur also teaches using sunflower oil, safflower, rapeseed, other vegetable oils, and marine oils, including fish (herring) oil (column 5) Additionally, Mazur teaches using 1,3-specific lipase, including lipase from *M.miehei*, including LIPOZYME (column 7; example III, column 8). Mazur further teaches carrying the molar ratio of components (column 7) and esterification at temperature of 20 °C to reflux for about 1-5 hours (column 7).

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Whereas Mazur is silent with regard to the specific proportions in the product, Mazur teaches the reagents including sunflower oil and behenic acid; the enzyme including 1,3-lipase, including 1,3-lipase from the instantly disclosed species *M.miehei*; and obtaining triglyceride(s) including those with conserved 1,2-, 2,3-, and 2-position residues and esterification with other fatty acid residues to produce a variety of triglycerides, including compositions which have C2 to C24 saturated or unsaturated fatty acid (esters).

Mazur teaches representative examples of forming a 2-position monoglyceride from a triacylglycerol (TAG) (e.g. Example I) and the representative example of forming diacylglycerides (DAG) and subsequently TAGs from the 2-position reagent (e.g. Examples II, IV, and V). Since Mazur teaches a finite number of fatty acid residues suitable for substitution into the product, and because selection of a plant oil such as sunflower oil would further narrow this selection to even-numbered fatty acids, it would have been obvious to make a composition having the instantly recited (individual) triglycerides based on the teachings of Mazur. Whereas Mazur is silent regarding all of the components of, for example, sunflower oil, the composition would be expected to intrinsically contain the claimed component fatty acids except for behenic acid in the claimed amounts.

Mazur is relied upon for the reasons discussed above. If not expressly taught by Mazur, based upon the overall beneficial teaching provided by this reference with respect to the equivalence and substitutability of the C2-C24 fatty acids including behenic acid in the manner disclosed therein, the adjustments of particular conventional working conditions (e.g., determining one or more suitable reagent ranges in which to perform a 1,3-lipase-mediated conversion to a 1,3-substituted TAG species), is deemed merely a matter of judicious selection

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from a finite set of fatty acids useful for the same purpose (forming DAG/TAG) and routine optimization which is well within the purview of the skilled artisan.

Whereas Mazur teaches using sunflower oil which consists of a complex distribution of TAGs, Mazur is primarily directed towards TAG formation. To this extent, it would have been obvious to combine individual TAGs because Mazur teaches that the TAGs embraced by the invention are useful for the same purpose (flavorants/aromatics) column 7, ¶7)). Furthermore there is nothing of record to recite a synergistic or unexpected property of the instant structured fat (TAG) and fatty acid compositions versus the mere combination of the elements towards a predictable summation/combination of the intrinsic properties of the individual components. Thus it would have been *prima facie* obvious to combine the TAG components taught by Mazur to obtain the claimed product with the claimed properties.

It would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g. *proportions and ratios of components and reagents* to produce a desired quantity of a particular TAG or fatty acid composition), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP § 2145.05).

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at

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the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed. Since new grounds of rejection have been raised above, the Office Action is **NON-FINAL**.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Kosar
Examiner, Art Unit 1651

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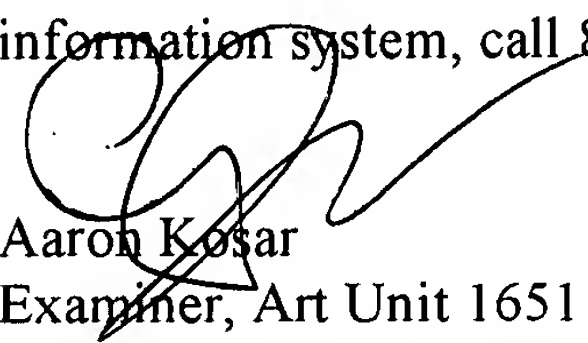
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